

## Remarks

The above Amendments and these Remarks are in reply to the Office Action mailed January 2, 2003. The fee for addition of new claims (or conversion of claims from dependent form to independent form) is included herewith.

Claims 90-98, 101-103, 105-108, 112 and 113 were pending in the Application prior to the outstanding Office Action. In the Office Action, the Examiner rejected claims 90-98, 101-103, 105-108, 112 and 113, and objected to claims 99, 100 and 104 solely as being dependent upon a rejected base claim. The present Response amends claims 90, 91, 95, 96, 99, 100, adds new claims 114-119, and cancels claims 92, 97, 112 and 113 leaving for the Examiner's present consideration claims 90, 91, 93-96, 98-108 and 114-119. Reconsideration of the rejections is requested.

### **I. REJECTION FOR NONSTATUTORY DOUBLE PATENTING**

#### ***Claims 90-96 and 101***

The Examiner rejected claims 90-92, 95, 96 and 101 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5, 16, 25 and 26 of U.S. Patent No. 6,149,652 to Zucherman et al. Further, claims 93 and 94 were rejected solely under the same doctrine over claims 2 and 3 of Zucherman in view of U.S. Pat. No. 5,549,679 to Kuslich. The Applicant respectfully traverses this rejection.

Filed along with this Response B is a terminal disclaimer in compliance with 37 CFR 1.321(c). Accordingly, the Applicants respectfully request the withdrawal of this rejection.

## II. REJECTION UNDER 35 U.S.C. §102(B) OVER BREARD (U.S. PAT. 5,011,484)

### *Claims 90-92, 95-98 and 101*

The Examiner rejected claims 90-92, 95-98 and 101 under 35 U.S.C. §102(b) over *Breard*. The Applicant respectfully traverses this rejection.

The Examiner describes *Breard* as disclosing “a method for stabilizing a spinous process (A) relative to another spinous process, where a device (1) is introduced between and conformed to the processes...the *pre-formed* device is made of an elastic or resilient material” (Emphasis added). The Applicants submit that *Breard* does not disclose all of the features of claims 90 and 91 because *Breard* fails to disclose either “a flaccid implant” as recited in claims 90 and 91, or “a device having flexible walls” as recited in claims 95 and 96. Referring to Figures 1-7, *Breard* describes an insert having a *pre-formed* shape that “takes the form of a small stud provided on its upper and lower faces, with a corresponding longitudinal groove....” See column 2, lines 67-68. *Breard* describes an insert having a defined shape, and fails to disclose a *flaccid* implant. Further, *Breard* discloses that the pre-formed shape “be made of a plastic material...” A solid, pre-formed implant lacks “flexible walls” as recited in claims 95 and 96.

Further, the Examiner describes *Breard* as disclosing that “the pre-formed device is made of an elastic or resilient material with a shape memory (polytetrafluoroethylene or PTFE)...” However, the Applicants respectfully submit that PTFE is not conventionally considered a shape memory material, nor does *Breard* explicitly disclose “a shape memory material.” Therefore, *Breard* cannot anticipate claim 98. The Applicants respectfully requests that the Examiner cite a reference in support of the Examiner’s position, as provided under MPEP 2144.03 with regard to official notice.

Still further, the Examiner states that “with respect to claim 101 the device [of *Breard*] has cavities (2, 3, 8) fillable with materials, such as the artificial ligament or portions of the spinous processes.” However, *Breard* fails to disclose the step of “sealing the cavity” as recited in claim 101.

In order for a reference to be properly applied under 35 U.S.C. §102(b) each of the elements of Applicants' method claims must be taught by the reference. *Breard* fails to teach each of the elements of the Applicants' method claims as discussed above, therefore *Breard* cannot anticipate claims 90, 91, 95, 96, 98 and 101. Accordingly, the Applicants respectfully request the withdrawal of this rejection.

### III. REJECTION UNDER 35 U.S.C. §102(E) OVER KUSLICH (U.S. PAT. 5,549,679)

#### *Claims 102, 103, 105, 106 and 108*

The Examiner rejected claims 102, 103, 105, 106 and 108 under 35 U.S.C. §102(e) over *Kuslich*. The Applicant respectfully traverses this rejection.

The Examiner describes *Kuslich* as disclosing "a device (146) in the vicinity of or about spinous processes, where the device has a first, loose configuration and a second, rigid configuration; and where the device is not connected to the processes." The Applicants submit that *Kuslich* does not disclose all of the features of claim 102 because *Kuslich* fails to disclose either "allowing the device to reconfigure to the second configuration, thereby *distracting* the spinous process and the another spinous process" (Emphasis added) as recited in claim 102, or "not connecting the device to either of the spinous process or the another spinous process" as recited in claim 108.

Referring to Figures 11 and 12, *Kuslich* discloses "bag containers 146...positioned against the bone of adjacent vertebrae...As time goes by, the containers will become very rigid and will be attached...to both vertebrae..." See column 9, lines 41-46. *Kuslich* discloses reconfiguring from a non-rigid to a rigid configuration, thereby fusing the spinous process and the another spinous process. *Kuslich* does not disclose "distracting the spinous process and the another spinous process." Further, because the containers fuse to both vertebrae, they are *connected* not just to one, but both the spinous process and the another spinous process.

Since *Kuslich* fails to disclose all of the features of claims 102 and 108, *Kuslich* cannot anticipate claims 102 and 108 under 35 U.S.C. §102(b). Dependent claims have at least the features of the independent claim from which they ultimately depend; therefore, *Kuslich* cannot anticipate dependent claims 103, 105 and 106 (which depend from claim 102) under 35 U.S.C. §102(b). Accordingly, the Applicants respectfully request the withdrawal of this rejection.

#### IV. REJECTION UNDER 35 U.S.C. §102(E) OVER VOYDEVILLE (U.S. PAT. 5,609,634)

##### *Claims 90, 91, 112 and 113*

The Examiner rejected claims 90, 91 112 and 113 under 35 U.S.C. §102(e) over *Voydeville*. The Applicant respectfully traverses this rejection.

The Examiner describes *Voydeville* as disclosing “a method for stabilizing a spinous process relative to another spinous process, where the method includes introducing between the spinous process a device (3 combined with 6) adapted to conform to a shape of a spinous process and sistract apart the spinous process.” The Applicants submit that *Voydeville* does not disclose all of the features of claims 90 and 91 because *Breard* fails to disclose “a flaccid implant” as recited in claims 90 and 91. Referring to Figure 7 and 8, *Voydeville* discloses a “ligament 1 and the block 6...considered *semi*-elastic because it is sufficiently flexible not to bring about any direct conflict with the bone and sufficiently *rigid* to maintain a certain distraction between the spinous processes.” See column 3, line 31 and column 4, lines 1-4. *Voydeville* discloses a rigid block, and fails to disclose a *flaccid* implant

In order for a reference to be properly applied under 35 U.S.C. §102(b) each of the elements of Applicants’ method claims must be taught by the reference. *Breard* fails to teach each of the elements of the Applicants’ method claims as discussed above, therefore *Breard* cannot anticipate claims 90 and 91. Accordingly, the Applicants respectfully request the withdrawal of this rejection.

**V. REJECTION UNDER 35 U.S.C. §103(A) OVER KUSLICH**

***Claims 105 and 107***

The Examiner rejected claims 105 and 107 under 35 U.S.C. §103(a) over *Kuslich*. The Applicant respectfully traverses this rejection.

To render a claim obvious under §103(a), a reference or a combination of references must teach or suggest all of the features of Applicant's claim. In view of the remarks in Section III above, the Applicant submits that *Kuslich* fails to teach or suggest all of the features of claim 102, from which claims 105 and 107 ultimately depend.

Since *Kuslich* fails to teach or suggest all of the features of claim 102, *Kuslich* cannot render claims 105 and 107 obvious under 35 U.S.C. §103(a). Accordingly, the Applicant respectfully requests the withdrawal of this rejection.

**VI. ALLOWABLE SUBJECT MATTER**

***Claims 99, 100 and 104***

In the Office Action, claims 99, 100 and 104 were allowed on condition that the claims be "rewritten in independent form including all of the limitations of the base claim and any intervening claims." The Applicant has amended claims 99, 100 and 104 to include the limitations of the base claim and any intervening claims. Accordingly, the Applicant requests that claims 99, 100 and 104 be allowed.

**VI. Addition of Claims 114-119**

The newly added claims are, it is submitted, allowable over the cited art.

## VII. Conclusion

In view of the above Remarks, reconsideration of claims 90, 91, 93-96, 98-108 is requested, as well as consideration of new claims 114-119. It is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: 9/2/03

By: \_\_\_\_\_

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